UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

JOINT MEETING OF THE
DENTAL PRODUCTS AND
EAR, NOSE AND THROAT DEVICES PANELS

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OPEN SESSION

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WEDNESDAY,
OCTOBER 6, 2004

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The panels met at 8:30 a.m. at the Hilton Washington, D.C./North, 620 Perry Parkway, Gaithersburg, Maryland, DR. A. JULIANNA GULYA, Chair of the ENT Panel, presiding.
PRESENT:

ENT PANEL:
A. JULIANNA GULYA, M.D., Chair
KAREN H. CALHOUN, M.D., FACS, Consultant
R. MICHAEL CROMPTON, J.D., M.P.H., RAC, Industry Representative
HERMAN A. JENKINS, M.D., Voting Member
ERIC A. MAIR, M.D., Consultant
LISA A. ORLOFF, M.D., Consultant
CAROLYN R. STERN, M.D., Consumer Representative
DAVID J. TERRIS, M.D., Consultant
GAYLE E. WOODSON, M.D., Consultant
SARA M. THORNTON, Executive Secretary

PRESENT (Continued):

DENTAL PRODUCTS PANEL:
JON B. SUZUKI, D.D.S., Ph.D., M.B.A., Chair
B. GAIL DEMKO, D.M.D., PC, Consultant
ELIZABETH S. HOWE, Consumer Representative
KASEY K. LI, D.D.S., M.D., Consultant
DANIEL R. SCHECHTER, ESQ., Industry Representative
DOMENICK T. ZERO, D.D.S., M.S, Voting Member
JOHN R. ZUNIGA, Ph.D., D.M.D., Voting Member

FDA REPRESENTATIVES:
A. RALPH ROSENTHAL, M.D., Director, Division of Ophthalmic and ENT Devices
M. SUSAN RUNNER, D.D.S., M.A., Chief, Dental Devices Branch, Captain, USPHS
ERIC A. MANN, M.D., Ph.D., Chief, ENT Devices Branch, Captain, USPHS
HEATHER S. ROSENCRANS, Director, Premarket Notification Staff
KEVIN P. MULRY, D.D.S., M.P.H., Dental Officer - Dental Devices Branch

I-N-D-E-X

AGENDA ITEM	PAGE
Call to Order A. Julianna Gulya, M.D., Chair	4
Introductory Remarks Sara M. Thornton - Executive Secretary	7
Conflict of Interest Statement Sara M. Thornton - Executive Secretary	10
Branch Updates Captain Eric A. Mann, M.D., Ph.D. - Medical Officer	12
FDA Presentation	19
Heather S. Rosecrans - Program Operations Staff	19
Captain Eric A. Mann, M.D., Ph.D. - Medical Officer	25
Kevin P. Mulry, D.D.S., M.P.H. - Dental Officer	45
Open Public Hearing Session	64
Panel Presentations	97
David J. Terris, M.D.	97
B. Gail Demko, D.M.D.	115
Panel Deliberations	145
Second Open Public Hearing Session	324

P-R-O-C-E-E-D-I-N-G-S

(8:39 a.m.)

CALL TO ORDER

CHAIRPERSON GULYA: I now call this joint meeting of the Food and Drug Administration Center for Devices and Radiological Health joint meeting of the Ear, Nose, and Throat Devices Panel and Dental Products Panel into session.

I see we have a number of individuals who are interested in today's meeting regarding the prescription versus the over-the-counter use devices intended to treat snoring and/or obstructive sleep apnea. And I am very appreciative of that.

I think we will quickly go around the table and perform introductions here, starting on my left here.

DR. ROSENTHAL: Ralph Rosenthal. I'm the Director of the Division of Ophthalmic and ENT Devices.

DR. RUNNER: I'm Susan Runner. I'm the Branch Chief of Dental Devices and the Deputy Director of the Division of Anesthesia, General Hospital and

Infection Control Devices.

DR. DEMKO: Gail Demko. I'm a consultant to the Dental Products Panel.

DR. CALHOUN: Karen Calhoun. I'm an otolaryngologist at the University of Missouri.

DR. TERRIS: Dave Terris. I'm a consultant as well. I'm at the Medical College of Georgia.

DR. WOODSON: Gayle Woodson, otolaryngologist, consultant, Southern Illinois University in Springfield, Illinois.

DR. ORLOFF: Lisa Orloff, consultant to the ENT Devices Panel from University of California, San Francisco.

DR. MAIR: Eric Mair, otolaryngologist from Wilford Hall in San Antonio, Texas.

MEMBER ZUNIGA: I'm John Zuniga. I'm a member on the Dental Panel from UNC, North Carolina.

CHAIRPERSON GULYA: Julie Gulya. I'm at the National Institute on Deafness and Other Communication Disorders.

EXECUTIVE SECRETARY S. THORNTON: Sara

Thornton, Executive Secretary for the Ear, Nose, and Throat Devices Panel.

MEMBER SUZUKI: Jon Suzuki, Dental Products Panel, Associate Dean at Temple University.

MEMBER JENKINS: Herman Jenkins, Otolaryngology, University of Colorado.

DR. LI: Kasey Li, consultant from Stanford Sleep Disorders Clinic.

MEMBER ZERO: Domenick Zero, Dental Products Panel, Associate Dean for Research, Indiana University School of Dentistry.

DR. STERN: Carolyn Stern, family physician, consumer rep for the ENT Panel.

MS. HOWE: Betsy Howe, consumer rep for the Dental Panel.

MR. SCHECHTER: Dan Schechter, industry representative for the Dental Panel.

MR. CROMPTON: And Mike Crompton, industry rep for the Ear, Nose, and Throat Devices Panel.

CHAIRPERSON GULYA: Okay. Thank you very much. Without further ado, I will turn it over now to Ms. Sally Thornton, our Executive Secretary.

INTRODUCTORY REMARKS

EXECUTIVE SECRETARY S. THORNTON: Good morning. On behalf of FDA, I would like to welcome you to the very first joint meeting of the Dental Products and Ear, Nose, and Throat Devices Panels in the Twenty-First Century.

(Laughter.)

EXECUTIVE SECRETARY S. THORNTON: Before we proceed with today's agenda, I have a few short announcements to make. I would like to remind everyone here to sign in on the attendance sheet in the registration area just outside the meeting room. All public handouts for today's meeting are available at the registration table.

Messages for panel members and FDA participants, information or special needs should be directed through Ms. AnnMarie Williams, who is available in the registration area. The telephone number for calls to the meeting area is (301) 977-8900.

In consideration of the panel and the agency, we ask that those of you with cell phones and

pagers either turn them off or put them on vibration mode while in this room and make your calls outside the meeting area. We strive to make this a cell phone-free room.

Lastly, will all meeting participants please speak into the microphone and give your name clearly so that the transcriber will have an accurate recording of your comments.

At this time, I would like to extend a special welcome and introduce again to the public and the panel and the FDA staff new panel consultants who are with us at the table for the first time: Dr. Gail Demko from the Dental Panel, Dr. Kasey Li from the Dental Panel, Dr. Eric Mair from the ENT Panel, Dr. Lisa Orloff from the ENT Panel, Dr. David Terris from the ENT Panel, and Dr. Carolyn Stern, the consumer rep for the ENT Panel. Those folks are joining us today for the first time.

There are two other announcements of note that I would like to make at this time. The first is to recognize that ENT Panel voting members, Dr. Julianna Gulya on my left here, who is Chair; Dr.

Herman Jenkins; and also Dr. Howard Francis, who is not with us today, and ENT industry rep, Mr. Michael Crompton, will serve on the ENT Panel today for the last time in that capacity. Their term expires on October 31st of this year.

We want them to know that their dedication to the work of the panel has been much appreciated. And we are very grateful for their willingness to serve. FDA owes you a resounding thank you for all you have given us. And we will be sending you a special remembrance for your service. Please join me in thanking them.

(Applause.)

EXECUTIVE SECRETARY S. THORNTON: The second is to announce the voting members who will begin their terms on 11-1-2004. They are Drs. Eric Mair and Lisa Orloff, whom you have just met, and Dr. Kathleen Sie, who is with the University of Washington in the Children's Hospital Medical Center in Seattle, Washington. Dr. Mair will be the new panel chair.

CONFLICT OF INTEREST STATEMENT

EXECUTIVE SECRETARY S. THORNTON: Now I

would like to proceed with the reading of the conflict of interest statement for this meeting. "The following announcement addresses conflict of interest issues associated with this meeting and is made part of the record to preclude even the appearance of an impropriety. To determine if any conflict existed, the agency reviewed the submitted agenda for this meeting and all financial interests reported by the committee participants.

"The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests. To determine if any conflict existed, the agency reviewed the submitted agenda for this meeting and all financial interests reported by the committee participants.

"The agency has no conflicts to report for today's agenda. However, we would like to note for the record that the agency took into consideration certain matters regarding Drs. Gail Demko, Eric Mair, and David Terris. They reported interests in firms at issue but in matters not related to today's agenda.

The agency has determined, therefore, that they may participate fully in all discussions.

"In the event that the discussions involve any other products or firms not already on the agenda for which an FDA participant has a financial interest, the participants should excuse him or herself from such involvement, and the exclusion will be noted for the record.

"With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products they may wish to comment upon."

Thank you, Dr. Gulya.

CHAIRPERSON GULYA: Thank you very much, Sally.

While proceeding along on our agenda, we will next hear from Dr. Eric Mann, who is the Chief of the Ear, Nose, and Throat Devices Branch.

BRANCH UPDATES

DR. MANN: Good morning, distinguished panel members, FDA colleagues, and guests. The last

meeting of the Ear, Nose, and Throat Devices Panel occurred in August of 2002. And we would like to take this opportunity to give you a brief update on the branch and some of its activities since that last meeting.

We have had a number of staffing changes within the branch recently. Aside from myself as Branch Chief, we have Ms. Karen Baker as our nurse consultant. We have two audiologist reviewers: Ms. Teri Cygnarowicz and Dr. James Kane. Dr. Vasant Malshet is our branch toxicologist.

And we are very pleased and privileged to have two new reviewers within our branch as of last fall. Dr. Srinivas Nandkumar is an electrical engineer with signal processing background. And Dr. Antonio Pereira is a practicing otolaryngologist/head and neck surgeon, who also serves as a part-time medical officer for our branch. And Dr. Pereira takes over for Dr. Sid Jaffee, whom some of you may recall has served our branch so well for the pst years. We wish Dr. Jaffee well in his retirement.

We have had one original PMA approved since the last panel meeting. The Karl Storz autofluorescence system was approved in December of 2002 for the indication of use of white light in autofluorescence bronchoscopy to identify and locate abnormal bronchial tissue for biopsy and histological evaluation.

The target patient populations for this new device are patients with suspected bronchogenic carcinoma, those previously diagnosed with lung cancer, and those patients who demonstrate abnormal sputum cytology, abnormal chest X-ray, CT scan, or other similar technology.

Here is a photograph of the entire autofluorescence system. On the left, you can see consists of a bronchoscope, a light source with a variety of filters, a camera, and a video output display monitor on the top. On the upper right-hand photograph, you see a photograph of the lower airways with white light used during a traditional white light bronchoscopy.

Below that, you see the same area

illuminated with the autofluorescence mode of the system. And you can see several areas of reduced autofluorescence, which indicate possible areas of abnormality and may require biopsy.

We have had quite a number of PMA supplements submitted since the last panel meeting. And I would like to share a few of the more important ones related to cochlear implants.

Cochlear Americas received approval for a design change to their electrode for their Nucleus 24 contour system. The new electrode is a longer, specialized electrode tip, which is shown here. The new electrode is called the soft-tip electrode. It features an advance off stylet insertion technique. I think you can see the stylet here on the left side of the figure. The new electrode tip is advanced off of that stylet into the cochlea with the aim of having a less dramatic insertion into the cochlea and ensuring a more consistent perimodiolar placement of the new electrode.

We also approved an advance off stylet insertion tool in October of 2003. It's shown here on

the left. This insertion tool is to be used with the new electrode and permits the surgeon to use a single hand insertion technique during the implant surgery.

MED-EL Corporation received approval in August of 2003 for a medium active electrode array. This new design features contact spacing, which has been optimized for special difficult cases of cochlear implantation, specifically those patients who have cochlear ossification or congenital malformations of the cochlea.

Like the standard array, it consists of 12 pairs of electrode contacts, but they are compressed together at the distal end of the electrode, as shown in this figure here, which facilitates a higher likelihood of complete insertion in these more difficult cases.

The company also received approval for an MRI indication. The device can be used with MRI at 0.2 tesla field strength. However, proper positioning of the patient within the magnetic field is necessary. And the imaging facility is directed to contact MED-EL prior to the MRI study to ensure that proper

procedures are followed during the MRI.

Finally, the third manufacturer of implants within the U.S., the Advanced Bionics Corporation, received approval for a major repackaging design change to their implantable cochlear stimulator, shown here on the left. The new stimulator is called the HiResolution Bionic Ear System, or HIRES 90K for short. It features a silicon-embedded titanium case. This is a smaller case compared to the previous generation of the CLARION device, which was made out of ceramic.

The agency also granted approved for a new HiFocus Helix precurved electrode, which is shown here on the lower left. The electrode achieves this precurved configuration, perimodiolar configuration, within the cochlea after removal of an insertion stylet.

Finally, the company received FDA approval for MRI compatibility with their device at field strengths of 0.3 and 1.5 tesla. Prior to the MRI study, the magnet within the implanted device has to be removed. The MRI study is conducted. And then the

magnet is replaced with minor surgical procedures.

As you may be aware, Advanced Bionics recently issued a worldwide voluntary recall of all unimplanted clarion and high-resolution bionic ear systems. The company undertook this action in response to the finding of moisture within the implant case of explanted devices, devices that had been explanted for either medical reasons or for device failures. In some cases, they were able to link the moisture within the implanted case with the actual device malfunction and failure.

The company is currently taking steps to address this by looking at their manufacturing processes, but in the meantime, FDA has worked with the company to draft notification letters for doctors, patients, and hearing health care professionals. These letters went out last week.

Of note, FDA is not recommending removal or replacement of normally functioning implanted devices. And the overall failure rate for these devices to date has been relatively low.

Finally, I am very pleased to announce

that within the next week we will be making available a CDRH cochlear implant Web site, with the Web link here.

The target audience for this cochlear implant Web site is current and prospective cochlear implant users, their parents, families, educators, and health care providers who may be involved with these users.

The content of the Web site includes information regarding cochlear implant design and function, including some very nice animated graphics, gives details about the cochlear implant surgery, and addresses some frequently asked questions. A very nice feature also is that it provides easy links to FDA regulatory approvals for these devices. So we think this will be a significant contribution to the resources out there available to the public on cochlear implants.

This concludes the branch update.

CHAIRPERSON GULYA: Thank you very much, Dr. Mann.

We do have a very tight morning schedule,

but I feel it incumbent upon us to at least be given the opportunity to have some burning questions answered. Are there any such burning questions for Dr. Mann before we proceed to Ms. Rosecrans?

(No response.)

CHAIRPERSON GULYA: Okay. Great. Ms. Heather Rosecrans, please? I think you were next on our schedule for a presentation. Most of you should have a copy of her slides as a handout.

FDA PRESENTATION

MS. ROSECRANS: Thank you very much.

I'm here this morning to just briefly discuss with you a subject that I am sure you are familiar with, which is prescription and over-the-counter use. I just want to give you a few examples and briefly go over the regulations we use to distinguish these two was of regulating and labeling devices.

Basically it surrounds adequate directions for use, whether or not there can be adequate directions for use written for a lay person. Generally we're looking at the sixth or seventh grade

level, considering how to write that labeling for a lay person, or if adequate directions for use cannot be written for a lay person, it would be considered a prescription device.

Our regulations, or actually our labeling regulations, are found in our Code of Federal Regulations in chapter 801. They describe the over-the-counter devices, again those for which directions for use can be written for a lay person, as well as prescription devices, which are exempt technically by our regulations, exempt from adequate directions for use, meaning for a lay person, but obviously they have directions for use for the licensed practitioners.

We also have what is considered under prescription devices prescription home use. So that would be a prescription device that you send home with the patient to use. for example, prothrombin time tests used in cardiovascular disease are given by the physician to the patient. They pick them up at the pharmacy and then use them in their home and report back to the physician.

If a firm had a prescription device and they wanted to market it over the counter, that would require a new application before the agency.

And, lastly, I wanted to mention that we do have many devices that are both prescription and over-the-counter. Someone can actually come in to use with a submission for a device that is both prescription and over-the-counter. The distinction would be how they are going to label the product. And obviously they would be packaging it differently as well, but it could be that's the very same device. A good example of this would be pregnancy test kits.

Okay. So obviously I'm sure you're very aware the over-the-counter devices are available for purchase directly by any lay person or consumer. And they involve self-diagnosis, et cetera. Again, they require adequate directions for use for that lay person.

A prescription device -- and this is the definition from our regulation -- is a device which because of any potentiality for harmful effect or the method of its use or the collateral measures necessary

to its use, it's not safe except under the supervision of a practitioner licensed by law to direct the use of such a device and, hence, for which adequate directions for use cannot be prepared, again meaning for a lay person. As I just said, they would be exempt for a lay person. And, again, they include those home use devices. That's considered prescription.

The labeling that we require in our regulations would be "Caution: Federal law restricts the device to sale by or on the order of a." And that's to be filled in with any one licensed by the state to use that prescription-type product. Okay?

And, again, the states enforce these prescriptions, even though the federal law requires the statements. Normally we allow the states to go ahead and enforce them because every state, as I'm sure you are very well-aware, is different in what they allow. And also the method of its application for use has to be addressed.

I just wanted to, lastly, just go over a couple of examples for you that you may be familiar

with. Recently, I think in September, we just cleared under the 510(k) process, actually, a device that went from prescription to over-the-counter.

And there was a public panel meeting in July. Those are the automatic external defibrillators. We just cleared our first over-the-counter one. Previously they were prescription and then prescription home-use. And, again, now we have cleared our first over-the-counter one.

I should also let you know that in the 510(k) program, which I know you have had training on, if a device has been cleared for prescription use and they want to market it as a prescription home use device and they make no other changes to the product, that would just involve they would be adding labeling for the home use environment. That does not require a submission to the agency if it's accepted medical practice in the United States. If in the PMA area it went from prescription to prescription home use, that does require a PMA supplement.

A couple of other examples of things that

we have in the near recent past cleared as over-the-counter would be the cryotherapy systems for warts have recently gone over-the-counter through the 510(k) process. As I said, pregnancy test kids; the prothrombin test again would be prescription home use. Ovulation predictor test several years back went over-the-counter through the 510(k) process.

And examples such as over-the-counter strep tests and over-the-counter gonorrhea tests have actually not been allowed to go to market at this time. It was determined the impact on public health was too great and had significant safety and effectiveness concerns. So, therefore, to date we have not allowed those over the counter. But, as you are aware, I am sure, we have allowed the AIDS test to go over the counter. And the risk-benefit decision for that was met before a panel.

So that's what I have for you today. Thank you.

CHAIRPERSON GULYA: Thank you, Ms. Rosecrans.

MS. ROSECRANS: Thank you.

CHAIRPERSON GULYA: Are there any questions at all from the panel?

(No response.)

CHAIRPERSON GULYA: Okay. Thank you very much. Next we will turn to Dr. Mann.

DR. MANN: Again, good morning and welcome to our distinguished panel members. This certainly is a rare opportunity for us here at FDA to have access to such a wealth of clinical experience from both the Dental and the ENT Advisory Panels. We very much appreciate your willingness to attend and prepare for this meeting and to share your knowledge with us as we consider important regulatory questions related to over-the-counter use of medical devices for the treatment of snoring and obstructive sleep apnea.

I would like to open this morning's session by giving you a brief history of the subset of ear, nose, and throat devices which have been proposed and in some cases cleared for over-the-counter treatment of snoring and obstructive sleep apnea.

The purpose of this slide is to basically demonstrate that although we have had many devices

cleared in the past for indications related to snoring or obstructive sleep apnea, we don't have a single division or branch within the agency that deals with that indication, snoring or obstructive sleep apnea.

In fact, we have at least four branches within our office that have been involved in a review of these devices. The Dental Devices Branch obviously would review things like oral appliances, jaw positioning devices, and also an assortment of other devices, such as palatal implants and the Repose tongue base suture system.

Our branch, the Ear, Nose, and Throat Devices Branch, has reviewed nasal dilators, cervical pillows, and a category that I will define a little bit later called mandibular support devices.

The Anesthesia and Respiratory Devices Branch has regulated the wide variety of CPAP devices currently out on the market, which are obviously a mainstay of OSA treatment.

And the General Surgery Devices Branch has regulated devices with more generic surgical applications, such as the lasers and the devices using

radiofrequency technology.

Now, despite the fact that these devices are all in different branches, I would emphasize that there is extensive formal and informal consultation that goes on between branches if there are clinical or technical issues that arise. And I would also emphasize for the purpose of the panel discussion today, we are not addressing CPAP devices and the surgical devices, which obviously would not be good candidates for an over-the-counter indication.

So, with that, I will be focusing my presentation this morning on the three categories up here on the left, which have been proposed for over-the-counter use. So I will begin with the nasal dilator, which is defined within the Code of Federal Regulations as a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal air flow. The device decreases airway resistance and increases nasal air flow.

These devices were the subject of an ENT

Devices Panel classification meeting back in October of 1990. At that time, it was determined that they would be regulated as Class I devices. I would point out that since that time, all of the indications that have been cleared pretty much have been over-the-counter indications. And the early indications mainly focused on things like reduction in nasal airway resistance and increase in nasal air flow.

This slide illustrates that the regulation also kind of breaks down nasal dilators into internal and external variations. The external variation, shown on the left here, basically consists of a skin adhesive coupled to a spring-like material. It is placed over the dorsum of the nose and pulls the lateral walls of the nose out laterally to expand the nasal airway over the region of the nasal valve. Here is an example of one, the Breathe Right Nasal Strip, which most of us are familiar with.

We also have a variety of internal nasal dilators, a good example being the Breathe With Eez nasal dilator shown here. It is a stainless steel

wire frame that is inserted into the nostril and basically supports and expands the distal nasal airway.

We also have on the market a device called Breathe EZ, which again goes into the nostril but in this time it's actually straddling the columella and compressing the septum bilaterally.

Finally, I would call your attention to the Nozovent device here at the bottom, which consists of a spring-like center strut and two flanges on either side. This is inserted into the nostrils and presses out laterally on the lateral nasal airway to expand the distal nasal airway as well.

As I mentioned on the previous slide, the indications for these devices early on basically centered on things like reduction in nasal airway resistance and increases in nasal air flow. But the Nozovent device down here at the bottom was actually the first device that came in seeking an over-the-counter snoring claim.

This was back in the early 1990s. The company recognized that the over-the-counter snoring

indication consisted a new indication for use, and they did submit a 510(k). Within that 510(k), they presented clinical data to support the safety and effectiveness of the Nozovent device for snoring.

While I can't disclose all of the contents of that submission, some of the data used to support the indication have been subsequently published, as shown here and basically showed a reduction in subjective snoring skills and so forth.

Based on the clinical data provided, the labeling submitted, and other information within the 510(k), it was, in fact, cleared in August of 1991 for an over-the-counter snoring indication. It obviously opened up the doorway for other nasal dilators to come in seeking a similar indication.

So following the Nozovent clearance, the FDA policy for nasal dilators seeking a snoring over-the-counter indication has been as follows. Assuming that the device has the same indications for use or very similar technological characteristics to the nose event or another suitable predicate device, no clinical data has been required to support a

snoring OTC indication. And typically what has been submitted are things like design specifications, material specifications, and some bench-top testing as appropriate to demonstrate substantial equivalence to that predicate device.

However, if there is new technology or new indications for use, they would have to come in with a 510(k) with clinical data. An example of that would be the Breathe Right Nasal Strip. When they came in seeking an OTC snoring claim, that was obviously different technology from the internal nasal dilator with the Nozovent device. So they did submit clinical data to support clearance of their snoring claim for over-the-counter.

Now, one of the things that happened in the late 1990s was the passage of the Food and Drug Modernization Act. And under the provisions of this act, the vast majority of Class I devices became exempt from pre-market or 510(k) notification. This, indeed, was the case for nasal dilators as well effective April of 1999. However, I would point out that this exemption is subject to limitations. And

any device which has new technological characteristics or new intended use would still be required to come into the agency with a 510(k) and clinical data to support the indication. I would point out that there have been no obstructive sleep apnea indications cleared for these devices to date.

FDA has reviewed the labeling for these products in the past for snoring indications and in general has ensured that the adequate labeling precautions and warnings are included. The exact wording of these precautions and warnings has varied somewhat, but in general they all instruct the patient to seek medical attention for any abnormal breathing patterns during sleep, pauses, and breathing, daytime sleepiness, difficulty breathing, gasping, choking for air at night, and so forth, things that would indicate potential for diagnosis of sleep disorder breathing.

In addition, the labeling has also included instructions to cease use if there is evidence of skin or mucosal irritation depending on whether it's an internal or external nasal dilator. The consumer is instructed not to exceed the

recommended duration of use for the product. And the product has been labeled not for use in individuals under the age of five.

I did a quick search of our computerized database of previously cleared nasal dilators that have been cleared for this snoring claim and came up with a quick list of about seven devices that we have within our database, but I would emphasize that since the FDMA was passed, many of the newer devices have not had to come in with a 510(k). So this is clearly not a complete list of nasal dilators out there on the market for snoring.

So that covers the nasal dilators. I'd like to next move to cervical pillows, which have also been regulated by our branch for these indications. Unlike nasal dilators, we have no classification regulation for cervical pillows for the indication of snoring or obstructive sleep apnea, but the agency has determined that these devices when they're marketed for either a snoring or an OSA indication do fall within the definition of a medical device because they're intended to affect the structure or the

function of the body.

In the early 1990s, we had quite a few 510(k)'s that had come in seeking a snoring indication. Based on the large potential number of 510(k)'s that would be coming in, the limited resources of the agency, and the relatively minimal risks associated with the direct use of a pillow, it was decided that FDA would exercise regulatory enforcement discretion for pillows being marketed for the snoring indication. I would emphasize this is for the snoring indication only, not for any other medical conditions, like obstructive sleep apnea.

So under this regulatory enforcement discretion policy, no 510(k) pre-market notification has been required for pillows just seeking the snoring OTC indication. There's been no enforcement of section 807 of the regulations regarding registration and listing requirements. These devices still are subject to adulteration and misbranding provisions of the Food, Drug, and Cosmetic Act. And FDA has always reserved the right to change this policy if determined to be necessary.

Now, this exercise of regulatory discretion has always been contingent upon the sponsor agreeing to some labeling conditions. As I stated before, there can be no other medical claims for the proposed device.

In addition, we have insisted that they include these warnings and contraindications, essentially the warnings, instruct the patient to seek consultation with the physician if they have signs or symptoms of obstructive sleep apnea, such as excessive daytime sleepiness or pauses in breathing similar to the labeling for the nasal dilators.

There were some contraindications that were required in terms of contraindicating patients with heart disease being substantially overweight. And the product had to be labeled for not for use by infants or children and to discontinue use if pain or discomfort results.

So this was the policy that was developed in the early 1990s. And since that time, many manufacturers have agreed to abide by these conditions and have been marketing their pillows for snoring OTC

conditions without submission of 510(k)'s to the agency.

The first cervical pillow that came to the agency seeking an OSA indication was the PillowPositive II Cervical Pillow. This was back in 1999. The sponsor was Life Sleep Systems. They had been one of the companies that had been marketing their pillow for the snoring indication under the terms of the regulatory discretion that I just described. But they did recognize that the OSA would be a new indication for use and came into the agency with the 510(k) seeking a claim for snoring and mild obstructive sleep apnea.

To support this indication, they submitted clinical data. Again, I can't go into detail about everything within the content of that 510(k), but some of that information has been published as well. I can include the references here. And I think one of these references is actually in the panel briefing packet, basically demonstrating reduction of respiratory disturbance index with use of the pillow compared to baseline conditions.

Based on the clinical evidence supplied within the 510(k), review of the labeling and so forth, this was, in fact, cleared in June of 1999 for both a snoring and mild obstructive sleep apnea indication. This clearance was for prescription use only.

There were several instructions regarding measurements that had to be taken of the patient, fitting of the pillow to the individual patient by the health care provider. So it was labeled as a prescription use only, and the sponsor did not request over-the-counter indication for this pillow.

The labelling for the patient did, in fact, contain the same warnings and contraindications that we have prescribed previously for snoring pillows and nasal dilators.

Now, since that time, we have had two cervical pillows that have also been cleared for a mild obstructive sleep apnea indication in addition to snoring. The first of these was the Popitz Pillow, which came in in 2002. It was similar to the previous pillow in terms of the technology of cervical

positioning to achieve increased patency and stability of the airway. This pillow essentially places the patient or the consumer in the snit position with neck flexed, head extended to stabilize and open the airway.

The 510(k) was, in fact, cleared for the snoring and mild obstructive sleep apnea indication in October of 2002. There were numerous factors that went into that decision-making process. First of all, the sponsor had submitted clinical data supporting the effectiveness of cervical positioning and mild obstructive sleep apnea, similar to the evidence presented in the previous slide.

There was a recognition that there may be some fuzziness or crossover between patients out there with primary snoring, snoring only in mild obstructive sleep apnea. We know that from night to night, there is a significant variation in patient symptoms and the results of studies from various centers using various criteria. So the distinction between snoring and mild obstructive sleep apnea is not always that clear-cut on individual patients.

Third, we had a long history of safe use for snoring pillows over the counter, as I will get to in a couple of minutes, but basically no significant adverse events have been reported to FDA for snoring pillows for the past ten-plus years.

Finally, it was felt that the sponsor had submitted adequate directions for use for an OTC indication. In particular, this pillow did not involve any sort of fitting or specialized measurements that had to be taken like the previous pillow. And it did include all of the warnings, contraindications, and so forth, in terms of instructions to seek medical attention for signs and symptoms of obstructive sleep apnea.

So kind of based on all of these factors, it was felt that adequate directions for use had been supplied in submission. And it was cleared in October of 2002. Since that time, we have received one additional 510(k) for the indication of mild obstructive sleep apnea and snoring. It's the Soma Pillow. It was cleared in April of this year based on clinical data with the pillows supplied by the sponsor

as well as consideration of the other factors mentioned for the Popitz Pillow.

So, in summary, we have basically three pillows cleared for mild obstructive sleep apnea, snoring, one of which is a prescription device and these two of which are over-the-counter.

I would like to finally move on to the category that we are terming "mandibular support devices." These devices are essentially those that support the mandible in the closed position. I downloaded some pictures of CPAP chin straps from the Web. This is basically what we're talking about when we speak of mandibular support devices. They're basically supporting the mandible in the closed position.

Like snoring pillows or cervical pillows, we have no classification regulation for mandibular support devices. In fact, we have received no 510(k)'s for these devices to date. The reason why I am mentioning them during this meeting is that we have received numerous informal queries from industry regarding the types of studies and the types of data

that would be required to support safety and effectiveness of these devices for either snoring and/or obstructive sleep apnea.

In general, the literature that has been cited in support of these types of devices are those such as I have shown here, which basically show that the mouth open position is associated with increased collapsibility of the upper airway and a narrowing of the airway, so the presumption being closure of the mouth with one of these support devices would enhance patency and stability of the airway. So I raise this as a possibility of things that we might be seeing in the future.

Finally, I would just like to give you a brief overview of our post-market adverse event experience with these three categories of devices. We did a search of our computerized database, the MAUDE database, which captures both voluntary and mandatory adverse event reports dating back to the early '90s. With respect to nasal dilators, we have had four adverse event reports.

Two were related to skin irritation with

the use of an external nasal dilator, nasal strip. One reported eye irritation related to use of a nasal strip, although it was unclear how the eye irritation was tied to use of the device.

Finally, we have one report of an internal nasal dilator that was actually displaced into the posterior nasal cavity. We have received no adverse event reports for cervical pillows for the snoring and obstructive sleep apnea indication to date.

Finally, even though we have had no 510(k)'s for the mandibular support devices, we do have one event reported in the database of transient airway obstruction in a patient using an illegally marketed device. They basically woke up gasping for air, pulled off the strap. Fortunately, there was no significant sequelae related to that, but it was reported in our database.

In general, the ten-plus-year experience with these devices has demonstrated that there have been relatively few adverse events reported. And those reported have, by and large, been minor in nature.

That being said, I think it's given that there is a significant under-reporting of minor adverse events. Dr. Mair has published a very nice study, prospective study, of experience in a patient population with these over-the-counter devices. As I understand it, a number of those patients experienced some minor adverse events. So I'm hoping this afternoon perhaps he can share the knowledge that he gained from conducting that study with us.

So that concludes my portion of the presentation. If there are no questions, I will turn things over to Dr. Kevin Mulry, who will be discussing the dental devices and their history.

CHAIRPERSON GULYA: I think in view of the time, we will proceed with Dr. Mulry's presentation. Then we can hopefully interweave questions after we have our open public hearing session before we dive into our deliberations. Thank you very much, Eric.

DR. MULRY: Good morning. I would also like to add my welcome to the panel and thank you for taking the time today to come and join us in this very important discussion of devices for the treatment of

snoring and/or obstructive sleep apnea.

EXECUTIVE SECRETARY S. THORNTON: Kevin, you can move that up to your mouth.

DR. MULRY: Thank you.

EXECUTIVE SECRETARY S. THORNTON: But we need you to speak closely into it.

DR. MULRY: Okay. Dr. Mann has presented the ENT Branch's perspective on the regulation of these devices. I am now going to present the Dental Branch's perspective on the regulation of these devices.

So the scope of the dental devices that we're going to discuss today includes intraoral devices only. They are devices that are fitted over the teeth and tongue and are removable. I want to reiterate that the discussion to date does not include implantable devices, surgical devices, CPAP, or diagnostic devices.

The regulatory history for the dental devices is that the panel met, the Dental Products Advisory Committee, met in November 1997 to classify intraoral devices for the treatment of snoring and

obstructive sleep apnea.

The panel recommended that these devices be classified into Class II with special controls in order to provide reasonable assurance of the safety and effectiveness of these devices. This means that sponsors need to submit a 510(k) or pre-market notification to the agency for market clearance. And a special Class II special controls guidance document was published in 2002 as the special control for this Class II regulation.

In some sponsors, one of the impetuses for the meeting today is that sponsors have requested that these devices be made over the counter. That is the reason we are asking for your input today as to what data sponsors should submit to provide reasonable assurance of safety and effectiveness for over-the-counter use for dental devices.

Intraoral devices are cited in the Code of Federal Regulations under 21 CFR 872.5570. The regulation states that intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to

reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction.

The agency published a Class II special controls guidance document, which I believe was provided in your panel packs. The document is intended to inform manufacturers regarding the data needed in a 510(k) submission. In developing this guidance document, the agency has considered it the least burdensome approach to resolving the statutory requirements.

The guidance document includes the risks to health generally associated with the use of these devices and recommends measures to mitigate the identified risks. The guidance document also includes recommendation for biocompatibility testing for the devices, clinical testing that may be needed based upon the individual devices, and labeling.

So what are the types of dental device designs for intraoral devices? The classification includes three basic designs: the tongue retaining

devices, the mandibular repositioning devices, and the palatal lifting devices.

The tongue retaining device are intended to increase pharyngeal space to improve the patient's ability to exchange air by supporting the tongue in an anterior position.

The mandibular repositioning devices are designed to move the mandible into a more anterior position and provide support for the jaw at rest. This is intended to create a larger airway space, thereby decreasing airway turbulence, tissue vibration, and airway obstruction.

The palatal lifting devices are designed to lift the soft palate, thereby increasing airway patency. The device is designed to support the soft palate, thereby decreasing tissue vibration and decreasing the intensity of the snoring.

Intraoral devices for snoring and obstructive sleep apnea have been cleared for the treatment of snoring and the treatment of snoring and/or mild to moderate obstructive sleep apnea but not severe sleep apnea, and they have been

prescription use only. All dental devices have been prescription use only.

This slide demonstrates some examples of the types of device designs. The one on the left is a tongue retaining device. It contains a bulb into which the tongue is placed. And the tongue is held in place by suction.

The mandibular aspect here is fitted over the teeth to stabilize the device. And the device is held in this anterior position through the pressure or the resting of this aspect of the device depending on the design against either the lips or the jaw. And also the mandibular aspect since it is fitted to the teeth also prevents the device from moving in a posterior direction.

The device on the right is a mandibular repositioning device. It depicts the mandible in an anterior position to centric occlusion or your normal bite.

You can see here that in the anterior area, there is an open space for oral breathing. That is one of the things that we have required in all of

the submissions for intraoral devices, that there be a mechanism for oral breathing since these devices can be somewhat obstructive due to the nature of the devices. And also we have concerns about those patients who might have nasal congestion.

I would also like to point out the mechanism for advancement on this type of device. It's a keyed type of mechanism, which can unless the device can be advanced either by the doctor or the patient and it's a very gradual type of advancement and may be able to advance due to 20 to 40 different types of physicians.

I would like to contrast that with the boil and bite mandibular repositioning devices that we are seeing today. These tend to be a thermoplastic material with slotted groves in the anterior of the mandible aspect or the mandibular tray. There's usually a pin or a stylus attached to the maxillary or upper tray that fits into the slot of the lower tray. This then has preset slots or preset advancement settings. And there are usually two or three types of settings on these types of devices.

Then on the right is the palatal lifting device, which has a button, which is gradually adjusted in a posterior direction back to the soft palate towards the uvula. This is done in a very gradual fashion because patients need to adjust their gag reflex to the presence of this button as it can be for many patients a difficult adjustment based upon the natural gas reflex. The button is intended to support the soft palate and, therefore, reduce the vibration of the soft palate and reduce the intensity of snoring.

Also, I want to go back just for a second and say that the amount of advancement that we usually see with these types of mandibular repositioning devices has a wide range. It is usually about 50 to 75 percent of the maximum protrusive position. The slotted mechanism is preset, and the advancements are usually approximately 4 to 5 millimeters for the treatment of snoring and approximately 8 to 10 millimeters for the treatment of obstructive sleep apnea.

So what are the trends the Dental Devices

Branch has seen in the few years with these devices? The majority of the early designs for the mandibular repositioning devices require that a dentist take an individual impression or a custom impression of each individual patient. They contain a lot of orthodontic hardware, hinges, wires, et cetera, and also that they had self-adjusting advancement mechanisms that could be adjusted by either the doctor or the patient.

The newer devices that we are seeing -- and there has been an increased interest in these -- are the boil and bite types of devices. These devices vary in design but tend to have in common that they have a thermoplastic material, which is heated and then placed in the patient's mouth. And they have preset advancement mechanisms.

This is important in that we will ask you, the panel, today to consider the different types of designs in the discussion of data that should be submitted to the agency if you were to recommend that over-the-counter devices be approved.

I just want to reinforce the concept of the differences in the types of designs. Again, the

one on the left is one that is a generic type of device. I will just use this, but there are many different types of devices with a lot more wires and a lot more complexity.

The issue here is that for this type of device to be fabricated, it needs the dentist to take an impression of the individual arches, both the upper and lower arches; requires that it be poured in stone; be sent off to a lab; the wires need to be fabricated to fit the individual patient; and then they need to add the advancement mechanism.

This is in contrast to the boil and bite types of devices that are noted here that you can see that there are slotted mechanisms on the mandible, some type of pin or stylus on the maxillary or upper aspect, which fits into the slots here.

So I just want to draw the contrast in the types of devices that we have. The boil and bite devices don't need to be sent to a laboratory, nor do they need to be customized for each individual patient.

The Class II special controls guidance

document made labeling recommendations that were based upon the discussion of the Dental Products Panel meeting in 1997. The guidance document lists contraindications of central sleep apnea since these devices, really, the intraoral devices, are intended for obstructive sleep apnea, not central sleep apnea, severe respiratory disorders, severe asthma, et cetera, concerns for obstructing the patient who may already be obstructed. Loose teeth or advanced periodontal disease, these devices, especially the mandibular advancement devices, put a lot of pressure on, in particular, the lower anterior teeth and the upper anterior teeth. And if a patient has loose teeth or advanced periodontal disease, it may compromise the dentition further.

We have contraindicated these devices in patients under 18 years of age because we do not believe that they should be used during the growth phases of the jaw and the TMJ. In edentulous patients, these are intended to be fitted over the natural dentition.

The guidance document also provides

warnings that the use of these devices may cause tooth movement or changes in dental occlusion. That may be a long-term effect of using these types of devices.

Dr. Demko will be presenting on those issues a little bit later, gingival or dental soreness, especially the ones that need to be individualized and custom impressions need to be adjusted for each individual patient to prevent impinging on the tissue.

And the pressure from the advancement may cause some dental soreness, pain or soreness of the TMJ with the advancement of the mandible. It may stress the TMJ or the muscles surrounding the TMJ, obstruction of oral breathing. And, as I have said, we have required a mechanism for oral breathing on all of these appliances in excessive salivation.

So what types of clinical studies has the Dental Branch been reviewing? For simple snoring, the studies have included performance measurements that include the rate of reduction of snoring based on clinical observation. This may be as simple as a recording of snoring pre and post-insertion of the

device measuring the intensity or loudness of the snoring.

For obstructive sleep apnea, the clinical data includes baseline and post-insertion polysomnograms measuring the apneic events, the apnea/hypopnea index, oxygen saturation, and other measurements. These data are provided in a 510(k) submission when there is a new design dissimilar from designs previous cleared in a 510(k), new technology, or new indication for use.

So what differences are there between the Dental Branch and the ENT Branch in regulating these devices? All dental devices for snoring and obstructive sleep apnea are intraoral, and all are prescription devices. That is, no intraoral dental devices for the treatment of snoring and/or obstructive sleep apnea have been cleared as over-the-counter devices.

Also, due to the dissimilarities in design, intraoral devices for both snoring and obstructive sleep apnea pose similar risks based on the correct selection and fitting of the appliance, as

opposed to perhaps an external nasal strip, for which fitting is not as critical as the selection of the correct device for the treatment of snoring and/or obstructive sleep apnea.

As noted in Dr. Mann's presentation earlier, the ENT Branch has cleared over-the-counter devices for snoring and mild obstructive sleep apnea.

So why has the Dental Branch cleared these devices as prescription-only devices? These devices present different risks perhaps from the ENT devices. The devices are varied in design. As I have discussed, there are three different designs that are included in the regulation to date. Within those designs, there are subsets of those designs. And also sometimes there are combinations of the designs in one device.

And the application based upon the degree of advancement may present some other risks. These devices apply forces on the teeth, tissue, and the temporomandibular joint, which makes correct selection and fitting of the device along with adequate follow-up important in preventing injury.

Critical care by a dentist is critical in the diagnosis of periodontal disease, decayed, missing, and filled teeth, the maximum protrusive range and the range at which the mandible should be advanced, the status of the temporomandibular joint, and also the diagnosis of parafunction, such as clenching, grinding, which may impact the type of device that is used and also the fitting of the individual device. All of these assessments are important to the safe use of these devices.

The Dental Devices Branch has received clinical protocols from sponsors to support over-the-counter use for the treatment of snoring and anticipate receiving protocols also for obstructive sleep apnea.

Some of the issues that have been addressed in these protocols include the intervention of a dentist or other competent intermediary to assess the general health status, the oral health status, and/or the appropriateness of the individual device prior to the patient receiving the device.

The Dental Branch has not viewed these

protocols as representative of consumer use studies for over-the-counter devices. For example, they do not seem to reflect the experience of a consumer going to a pharmacy, picking a device up off the shelf, taking it home, reading the directions, fitting the device accurately, and then being able to make an assessment as to whether the device is the correct device and also whether the device is effective.

Other issues discussed in these protocols include lay person self-assessment of snoring versus obstructive sleep apnea and directions for use for self-fitting the oral appliances and self-assessment of the fit.

These are issues that we would like your input in your discussion today to assist us in determining what would be adequate protocols to support over-the-counter use of these devices.

As Heather Rosecrans presented earlier, over-the-counter devices require adequate directions for use for the lay person. The questions that have come to the Dental Branch's mind in looking at these devices are: Can the lay person accurately

self-diagnose their medical condition? Can the lay person accurately self-diagnose their oral health status? And can the lay person choose the correct oral appliance and fit it accurately such that the device is safe and effective and does not cause adverse events? And also are there different considerations for snoring versus obstructive sleep apnea?

We have developed some questions to assist you in your discussion today. What I would like to do is present the three questions that we have developed. These questions apply both to the dental and ENT devices and just hopefully will focus the discussion to assist us in gathering the information that we would hope to receive today.

Question 1 is, as noted in FDA's presentation, the following types of devices may be considered for or have already been cleared for over-the-counter status for the indications of snoring and/or obstructive sleep apnea. Please discuss the risks and benefits of allowing devices to be marketed over the counter for the treatment of snoring and also

mild, moderate, and severe obstructive sleep apnea.

And, in particular, please discuss the overall risk-benefit ratio assessment as it relates to the level of disease severity and discuss the potential risks related to delay in professional diagnosis and treatment resulting in over-the-counter availability or use of these devices.

We have developed a chart to go along with question 1, which lists the different types of devices, and then the snoring and the different degrees of obstructive sleep apnea and whether these devices have been presently cleared as prescription or over-the-counter devices.

Question 2, if after your discussion of question 1 you believe that certain devices would be appropriate for over-the-counter treatment of obstructive sleep apnea, please discuss the following: how adequate product labeling can be written to assist the user in self-diagnosing and differentiating the severity of obstructive sleep apnea he or she is experiencing to ensure proper use and also any other general or specific labeling restrictions which you

believe would be appropriate for over-the-counter devices to treat snoring and/or obstructive sleep apnea; for example, any specific types of contraindications, warnings, or precautions which you believe should appear in the device labeling.

And then the final question is, please discuss the following aspects of the clinical data which may be appropriate to be included in marketing submissions for snoring and/or obstructive sleep apnea: a) the general clinical study design, including control group, if needed; b) the endpoints which would be acceptable for the assessment of the effectiveness of treatment; c) the degree of improvement for each of the endpoints which would be clinically meaningful assuming an acceptable adverse event profile; d) the specific adverse events, if any, which should be carefully assessed by FDA from the clinical trial; e) whether any of the responses to 3(a) through 3(d) would be different based on the severity of snoring and/or the degree of obstructive sleep apnea: mild, moderate, or severe; f) any specific considerations in trial design for

over-the-counter indications; and g) any specific device types or indications which would not require clinical data. Again, we will put these questions up later for you to assist you in your discussion of this topic.

I want to thank you for the opportunity to present today. And I will answer any questions if you want.

CHAIRPERSON GULYA: Thank you, Dr. Mulry. I think in view of the time, what we will do is we will hold questions for all of you speakers, Ms. Rosecrans, Dr. Mann, and yourself, of when we start to embark upon our deliberations. So thank you very much.

DR. MULRY: Thank you.

OPEN PUBLIC HEARING SESSION

CHAIRPERSON GULYA: Next on the agenda is the open public hearing segment, for which we have 30 minutes allocated.

While I am going through the rest of this material, I see that we have five presenters listed here: Dr. Steven Merahn, Dr. Lawrence Epstein, Dr.

Kent Moore, Dr. Keith Thornton, and Mr. George Dungan. If you would be so kind as to arrange yourselves in an order so you could be proximal to the microphone so as to minimize transition time in between speakers, that would much appreciated.

The open public hearing segment provides the opportunity for members of the public who have an interest in addressing the panel on today's topic; i.e., over-the-counter/prescription use for devices for the treatment of snoring and/or obstructive sleep apnea.

Each presenter should state clearly for the record their name; affiliation; interests in the topic at hand; any consulting arrangements or financial interest with medical device firms; and if travel expenses have been paid, by whom.

Now, I have been asked by the FDA to read this into the record. This is the introduction to the open public hearing general matters meeting. Both the Food and Drug Administration and the public believe in a transparent process for information-gathering and decision-making. To ensure such transparency, at the

open public hearing session of the Advisory Committee meeting, FDA believes it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written and oral statement to advise the Committee of any financial relationship that you may have with any company or any group that is likely to be impacted by the topic of this meeting. For example, the financial information may include a company's or group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

So, as I said, we have 30 minutes for this session. We have a number of speakers. And I understand all of you have been asked to hold your comments to five minutes. And out of fairness to all,

I ask you that you hold yourself to these limits.

I do have one of these neat little timing devices that hopefully I can use without blowing this all up. We will try and use that to help encourage us to stay on time.

So we have as our first open public speaker Dr. Steven Merahn.

EXECUTIVE SECRETARY S. THORNTON: Either the podium or the table, whichever is more comfortable for you.

DR. MERAHN: Good morning, everybody. Thank you.

EXECUTIVE SECRETARY S. THORNTON: Dr. Merahn, do you think we could dispense with the slides at this time in the interest of time?

DR. MERAHN: I don't have slides. I'm just going to read off my screen instead.

EXECUTIVE SECRETARY S. THORNTON: Okay. Fine.

DR. MERAHN: No, I wouldn't put you through that. I'm a no PowerPoint.

EXECUTIVE SECRETARY S. THORNTON: Okay.

I wanted to make sure you got your full five minutes here.

DR. MERAHN: Okay. Good morning, everybody. Thank you. Thank you for allowing me to present today.

I am a physician and founder of the American Academy of Sleep Disorders Dentistry, which is a private education and professional services organization with the objective of increasing the number of patients identified and treated for airway-relate sleep disorders via collaboration between physicians and dentists.

It is our position that a collaborative interdisciplinary approach to sleep disorders management offers the most responsible and effective means of reducing the significant public health and economic impact of obstructive apnea.

Our founding members include over 40 dental and medical professionals from all over the country, mostly from working knowledge in the use of oral appliances for the treatment of sleep disorders as well as TMJ and other forms of craniofacial pain.

The academy is almost entirely funded by fee for service for educational and professional activities. I have no other related conflicts of interest. And, in fact, the funding for my trip today came out of my own pocket.

The specific question at hand today is whether oral appliances for airway-related sleep disorders, such as snoring and sleep apnea, should be permitted to be sold over the counter or should remain prescription devices.

On that question, our recommendation is that they remain prescription devices, largely because: first, the risks of self-diagnosis are too high. There was a complex differential diagnosis associated with the signs and symptoms of airway-related sleep disorders, the primary symptom excessive daytime sleepiness, is a symptom of many serious medical conditions, including anemia, hyperthyroidism, and others.

While we do not believe that a full polysomnography is required to diagnose an airway-related sleep disorder, a trained health

professional and in our vision a physician-dentist team should be involved in the screening, assessment, and diagnostic process.

Second, there are potential adverse events related to the airway jaws. Tongues and teeth tend to be associated with unmonitored mandibular positioning. Oral appliances are serious therapy and can have a significant adverse impact on airway function if not properly fitted for optimal therapeutic efficiency. There is no one size fits all solution. The literature is quite clear that the efficacy is largely a function of the degree to which the appliance is titrated to patients' anatomy.

However, the issues underlying the specific question in front of you today should not be lost. The interest in over-the-counter status for oral appliances is driven by the compelling need to manage the overwhelming public health threat posed by airway-related sleep disorders.

As I am sure the Committee is aware, sleep apnea affects millions of individuals, more than asthma and diabetes and is increasingly recognized as

a cause of hypertension and cardiovascular events as well as impairments of cognitive function, interpersonal relationships, and workplace productivity.

Our academy recently commissioned a study which looked at the public health and economic impact of current treatment paradigms compared to our collaborative therapy model. While these data are being prepared for publication, I would like to share one or two conclusions with the Committee.

While CPAP is the gold standard of treatment with virtually 100 percent efficacy after titration, the data on compliance does not support CPAP as meeting the public health needs related to apnea.

There are some patients who with a more properly fitted and evaluated oral appliance will offer 100 percent efficiency without the burden of disruption of CPAP, but for even those who do not receive 100 percent efficiency, there is a compelling reason to use oral appliances to manage OSA.

Our study developed a population impact

factor for each therapy, a therapeutic index derived from fixed appliance data. For oral appliances, the impact factor is 60 percent. While CPAP is approximately 45 percent, this population impact factor is derived from efficacy and compliance data.

Based on these findings, oral appliances should be repositioned, so to speak, as a first-line therapy in a step-wise approach to management using a collaborative primary care model. This will significantly reduce the costs associated with sleep apnea.

Untreated apnea adds approximately $1,800 to the lifetime costs associated with MI and stroke. Based upon our population impact factor, oral appliances will lower that cost to $650 while CPAP actually only lowers it to $993.

If we substitute oral appliances for any percentage of patients entering the system, we will save significant amounts of money with little epidemiologic impact. In fact, the academy supports the increased use of oral appliances as first-line treatment for airway-related sleep disorders in a

collaborative care model but does not support their becoming available over the counter.

And while this may not be in the Committee's purview, we recommend shifting the responsibility for the treatment of apnea to an interdisciplinary team of physicians and specially trained dentists as a method to achieve the public health objectives but alleviate the risks of self-diagnosis and unmonitored treatment associated with OTC oral appliances.

Thank you.

CHAIRPERSON GULYA: Thank you very much.

DR. MERAHN: I can breathe now.

CHAIRPERSON GULYA: Yes, you can. Any pressing questions from the panel for Dr. Merahn?

(No response.)

CHAIRPERSON GULYA: Okay. Thank you very much.

DR. MERAHN: Thanks.

CHAIRPERSON GULYA: We will next proceed to Dr. Lawrence Epstein.

DR. EPSTEIN: Good morning. Thank you for

the opportunity to speak on this issue. My name is Larry Epstein. I am Board-certified in sleep medicine and head a sleep medicine specialty group in Boston, Massachusetts. I am instructor of medicine at Harvard Medical School and the President-Elect of the American Academy of Sleep Medicine, the organization I am representing today and who has paid for my travel expenses.

The AASM is the professional organization for the subspecialty of sleep medicine. The AASM publishes practice guidelines and diagnostic criteria to help provide the best care for patients with sleep disorders.

I have no other financial conflict of interest with respect to the issue of oral appliances.

Our organization and the individuals it represents are concerned about the consequences of possible over-the-counter use of oral appliances to treat snoring and obstructive sleep apnea. Making these over-the-counter devices will increase their availability but likely will not improve the care of patients with obstructive sleep apnea.

Oral appliances are valuable tools in the treatment of sleep apnea. Multiple studies have shown their effectiveness for mild to moderate but not severe obstructive sleep apnea.

A review by the AASM using strict evidence-based review methodology, which is included in our packet to you, which you should have, found that oral appliances, though not as effective as continuous positive airway pressure, were effective in over half of the patients with sleep apnea. However, they are not uniformly effective and have some significant complications. For these reasons, the use of oral appliances requires thorough evaluation and follow-up by medical and dental personnel.

Several more recent reviews, which include randomized trials in larger numbers, have reaffirmed the findings in the original review paper.

I would like to address two specific questions from the Committee, though I have tried to answer all of the questions in my written submission to you. First, what is the ability of the patient to self-diagnose and treat sleep apnea? The most common

symptoms of OSA are snoring and daytime sleepiness, which are sensitive but not specific for sleep apnea. People trying to eliminate their snoring are often not aware that snoring is a marker for the presence of sleep apnea.

Differentiating snoring from OSA can be difficult for a trained physician, much less the patient. For example, in a young, non-obese person under 40 years of age, body mass index of less than 27, whose only symptom is snoring with no daytime sleepiness or episodes of observed stopping breathing at night, the chance of having obstructive sleep apnea can still be up to 25 percent.

Additionally, since obstructive sleep apnea occurs while the person is asleep and unaware, people are poor judges of the presence of sleep apnea. Use of an over-the-counter oral appliance may improve the symptom of snoring but leave the apnea untreated.

I feel our organization is particularly well-suited to answer the next question. What is the role of medical and dental providers in the diagnosis, treatment, and follow-up of snoring and sleep apnea?

It can be difficult to differentiate between snoring and sleep apnea by symptom alone. Multiple studies have shown that thorough clinical evaluation plus objective testing, such as a sleep study, are required to establish both the presence and severity of OSA accurately.

Patients who try to eliminate their snoring with an over-the-counter device might delay or avoid appropriate evaluation and remain untreated for sleep apnea. This increases their risk of developing hypertension and other cardiovascular diseases and increases the likelihood of workplace and automobile accidents due to preventable hypersomnolence.

The FDA has approved over 30 oral appliances for the treatment of sleep apnea or snoring. They have different mechanisms and different degrees of change in airway shape. It is essential that a dental professional trained in the role of oral appliances and the treatment of sleep apnea and snoring as well as all aspects of oral health and dental occlusion be involved in determining the appropriate device and ensuring appropriate fit.

Although effective and well-tolerated, oral appliances are not always successful, often require modification, and have both mild and significant complications. Jaw and teeth discomfort and excessive salivation are commonly reported and can be resolved with dentist-supervised adjustment of the device.

Later complications include temporomandibular joint discomfort and changes in occlusive alignment, which can lead to chronic pain and difficulty eating. Follow-up by medical and dental care providers is essential for prevention and treatment of these problems.

Because oral appliances are not successful at eliminating sleep apnea in everyone, it is essential that the patients be checked for effectiveness of the device. Partial but ineffective treatment can mask the preventive symptom of snoring while leaving the most serious sleep apnea untreated.

The AASM has published a clinical practice parameter based on evidence-based literature review to guide practitioners in the use of devices. This paper

is also in your packet.

Our recommendations include the following. One, the presence or absence of sleep apnea must be determined before initiating treatment. Two, oral appliances should be fitted by qualified personnel who are trained and experienced in the overall care of oral health and temporomandibular joint, dental occlusion, and associated oral structures.

Oral appliances may aggravate TMJ disease and may cause dental misalignment and discomfort. Follow-up care by dentists is necessary to assess the development in any of these complications.

In summary --

CHAIRPERSON GULYA: Okay. Thank you. Summarize real quick, please.

DR. EPSTEIN: Okay. Oral appliances are valuable tools, but they need to be applied and managed by physicians and dentists trained in the treatment of sleep disorders and the management of dental health. Our organization and the practitioners it represents requests that you not change the guidelines at this time and do not make them

over-the-counter devices.

Thank you.

CHAIRPERSON GULYA: Thank you. Next we will hear from Dr. Moore.

DR. MOORE: Good morning. My name is Kent Moore. I am a Board-certified oral surgeon. And a segment of my practice in Charlotte, North Carolina focuses on treating patients with sleep-related upper airway breathing disorders. I am the mediate past Chairman of the American Association of Oral and Maxillofacial Surgeons Clinical Interest Group on Sleep-Related Breathing Disorders and Obstructive Sleep Apnea and currently serve as the President of the Academy of Dental Sleep Medicine.

The ADSM, the international organization representing general dentists, physicians, oral surgeons, orthodontists, prosthodontists, and pedodontists sharing a specific interest in oral appliance therapy and jaw surgery for treatment of sleep-related breathing disorders, is grateful for the opportunity to address the FDA regarding consideration of over-the-counter use of oral appliances.

I have no financial interest in this discussion, and my travel expenses have been paid for by my academy.

The ADSM is strongly opposed to OTC use of oral appliances and feels that allowing OTC use would present a significant risk to the greater public health. We do not feel there is sufficient data form the body of scientific and professional literature that substantiates the safety and efficacy of oral appliances utilized in this manner and recognize that unsupervisied utilization of these types of appliances will cause significant morbidity to the population involved as well as have detrimental effects in preventing or delaying the diagnosis and proper treatment of the underlying sleep-related upper airway disorder.

The explanation for this position is clarified blow in our response to the specific questions asked by the panels. That is, what is the role of the medical/dental provider in the diagnosis, treatment and follow-up of snoring and sleep apnea?

The ADSM's clinical treatment protocol,

which is attached in our written documents, documents our position that the diagnosis or absence of OSA and differentiation of primary snoring from OSA can only be performed by a qualified sleep physician and treatment therein coordinated and directed by the diagnosing sleep physician. Referral from the sleep physician after proper diagnosis is made to the treating dentist is necessary prior to fabrication of an oral appliance. These recommendations adhere to the current American Academy of Sleep Medicine Clinical Practice Parameter.

Much of the effort of the ADSM is directed toward training our membership regarding the complexities of upper airway pathophysiology and need for sleep medicine. In order to modify complications of therapy, once an oral appliance has been fabricated, the patient must be followed clinically for the length of time that the appliance is being utilized.

What is the ability of the patient to self-diagnose and treat obstructive sleep apnea? Properly diagnosing the presence and severity of upper

airway disorders is a complex and potentially complicated exercise. The position of the ADSM is that accurate self-diagnosis on the part of the patient is not a reliable method for diagnosis.

People trying to eliminate their snoring are often not aware that snoring is a marker for the presence of OSA. Differentiating snoring from OSA can be difficult for sleep physicians without the use of objective testing, much less an untrained person.

Use of OTC oral appliances may improve the symptom of snoring but leave the OSA untreated, exposing the person to the risk of developing hypertension and cardiovascular disease as well as increased rates of workplace and motor vehicle accidents.

Also essential prior to treatment is the need for proper diagnosis of the severity of the upper airway disorder in order to help direct the proper intensity of therapy. The literature documents that oral appliances are statistically more beneficial in patients with mild to moderate OSA; whereas, those patients with more severe degrees of OSA possess a

less statistical chance of obtaining a cure with oral appliance therapy.

Allowing any user to obtain an OTC version of an oral appliance and treat themselves without proper diagnosis exposes many patients to potential under or inadequate treatment of their airway disorder.

Additionally, when a user fails to get an adequate response from a fixed position OTC version of oral appliances, their willingness to pursue a more professional and therapeutic version of an oral appliance will most likely be tempered.

Data regarding safety and efficacy of oral appliances utilized in this OTC manner, preferably performed by entities devoid of a profit motive or other conflicts of interest, would be required prior to an OTC intended use decision. Data to this effect is currently lacking. The long-term impact of oral appliance therapy on TMJ function within the body of scientific literature also is currently lacking.

Adequate device labeling would require complete descriptions of the symptoms, causes, and

consequences of obstructive sleep apnea; the need for appropriate medical evaluation for OSA, including the differentiation of primary snoring from OSA and the relationship of snoring to OSA; and an overview of the mechanisms of oral appliances.

Consumers would need to be warned that treating their snoring may not eliminate OSA, even without other symptoms being present, resulting in silent apnea. Patients should be advised to contact their health care providers for any suspicion of OSA or if the devices are unsuccessful in eliminating snoring.

Consumers would also need to be warned of the following serious potential adverse events, as mentioned by a previous speaker. True, there are OTC appliances available to the public for treatment of tooth grinding or bruxism, but these appliances are not being asked to do what an advancement appliance is doing and do not bear the same type of forces being brought to bear for patients with OSA. Considering these forces, the potential for adverse effects is greatly magnified compared to these bruxism or mouth

guard appliances.

In conclusion, the ADSM strongly opposes making oral appliances available for OTC use. Oral appliances can be effective therapy for snoring and OSA, particularly in mild to moderate, severe OSA. However, the difficulty in differentiating between OSA and snoring, the need for clinical evaluation and physiologic testing and the potential for significant complications listed above, particularly in lieu of clinical data showing safety and effectiveness in an OTC model, make it essential that oral appliances be provided under the direction and care of medical and dental personnel trained in the management of patients with sleep disorders.

CHAIRPERSON GULYA: Thank you, Dr. Moore.

Any questions from the panel for Dr. Moore?

(No response.)

CHAIRPERSON GULYA: No. Okay. Thank you.

Dr. Thornton?

DR. K. THORNTON: Thank you. I'm Dr. Keith Thornton. I'm in the private practice of

dentistry in Dallas, Texas. I am the owner of Airway Management, Incorporated, which makes the TAP oral appliance.

I also have a number of other inventions. I am now part of the visiting faculty at Baylor College of Dentistry Department of Orthodontics. I have taught there in treating temporomandibular disorders and have taught at Pankey Institute the last 30 years. I am a consultant to Wilford Hall and to the Army in oral appliances and have worked for a number of people, including the Academy of Dental Sleep Medicine.

My issue today really is to come and say as a practitioner, I have treated probably 300 patients a year for the last ten years. And I have given some pictures to you of the morbidity that is caused by these devices. The device that I have developed can move the jaw beyond maximum protrusion in what we call passive stretch position, must beyond.

If you look at the publication by Jeff Pancer and the editorial afterwards, it says now that we can treat severe sleep apnea -- and that is what we

are treating. That is who I treat. I treat the people that are non-compliant severe sleep apneics.

In that picture, as you see, the patient was a 95-year-old patient that is in Class I occlusion when I started treating him in '93. By '97, he was seven millimeters forward of that position. And that was a permanent position.

He stopped wearing the appliance in about '99 to 2000. And he has not worn the appliance since. He has no sleep apnea, and it is almost like I did orthomatic surgery on him.

I have seen that in about four and a half percent of my cases. It is a frightening thing when we see that. I have decided not to take my device and make it even a non-custom appliance because I do not feel that it needs to be in the hands of anybody that is a non-dentist. And I am talking about physicians, anybody else that is a non-dentist, even a professional. So my determination as a company is to keep it within the dental profession.

As far as the warnings and labeling, we have just finished going through our booklets on

clinician instructions and made a lot of changes, including in our packets, some really significant things that I think are important.

One of these you will see in the next pictures over are pictures of what we call our exercise bite tabs. They go into every one of our boxes. And it's one of the things that when I teach dentists -- and I have taught at all of the meetings. I said the most critical thing that you do every morning is get the mandible back in the right position and teach the patient so that they can feel their back teeth every morning. If they don't do that within three weeks, I've seen it where they cannot get their teeth back into centric occlusion where they can't get their back teeth together.

We are now working with the head of the Orthodontic Department and looking at doing dog studies in effecting what we are really doing with this jaw joint and how it functions. It can cause very significant morbidities. As a practitioner and as a manufacturer, I don't think it is ethical for me to come out with something that is any less than a

device that is made by dentists.

Thank you.

CHAIRPERSON GULYA: Thank you very much, Dr. Thornton.

Do we have any questions for Dr. Thornton?

(No response.)

CHAIRPERSON GULYA: Thank you. And, lastly, we will have Mr. George Dungan.

MR. DUNGAN: Thanks very much for the opportunity to participate today. Respironics is a leading manufacturer of sleep and respiratory products. I'm the manager of clinical affairs, and I'm here in that capacity.

Our focus at this meeting concerns two important opportunities to improve patient care; specifically, over-the-counter treatment of snoring with appropriately tested and effectively used oral appliances and over-the-counter use of screening tools for sleep apnea. As you have heard, sleep disordered breathing affects millions of Americans and is largely under-diagnosed and under-treated.

Obstructive sleep apnea affects at least

18 million Americans, with up to 80 percent undiagnosed currently. At the other end of the sleep disordered breathing spectrum, snoring is a noxious condition that often prompts some intervention or at least accommodation by sufferers.

Many OTC treatments are promoted for the treating of snoring, although none have proved clinical evidence as to their overwhelming efficacy. On the other hand, efficacy has been established by the many prescription devices that have been cleared by the FDA to treat snoring. Many of these are oral appliances, the safety and efficacy of which have been demonstrated through clinical trials over the past ten years.

OTC clearance for oral appliances to treat snoring focuses on two questions: first, whether the treatment of snoring would prevent a user from seeking treatment for a potentially more serious condition, such as OSA; and, second, whether a user can successfully choose, fit, and treat the snoring on their own. Both of these risks are mitigated through education and labeling.

The ability of adequate instructions in labeling to permit the safe and effective use of OTC products has been demonstrated by the numerous clearances associated with other OTC medications and devices. These products show that consumers can readily understand when a medication or device is right for them, how to properly use the product, and when to seek medical assistance.

The same model can be applied to an OTC oral appliance. Such devices will need to include specific warnings and educational information for determining proper fit and use of the appliance.

Further, labeling and instructions should help users identify obstructive sleep apnea. The instructions should direct patients to seek medical attention if they currently have symptoms of OSA, if their condition does not improve, or if they experience discomfort or side effects from use of the device. We believe that any OTC device must also include a clear directive to the patient to include the appropriate clinician as a partner, even in their self-treatment.

FDA clearance of an OTC oral appliance should be supported by adequate clinical data, demonstrating the safety, efficacy, and useability of the device. These data would need to be submitted to the FDA for review prior to clearance and should address the following: compliance with FDA guidance on oral appliances; studies of long-term effects of continuous use of the device; demonstrated therapeutic efficacy; and, finally, demonstrated useability.

An important consideration for the use of OTC appliances is the adequate identification of the likelihood of obstructive sleep apnea. Thus, OTC screening for OSA is tied to these appliances. Patients pay a key role in their own transition for personal awareness to diagnoses. To help aid in that transition, we feel that tools raising awareness can help patients overcome that barrier.

The availability of at-home OTC screening devices for OSA will enable patients to move more readily towards appropriate diagnosis and treatment by a clinician. Failing to substantially address OTC screening may, in fact, perpetuate significant

under-diagnosis of OSA.

Such OTC devices for use in the home by untrained patients would need to meet several requirements. First, the device must have the appropriate level of sensitivity to identify sleep apnea while maintaining a low rate of false negatives. Manufacturers should provide the FDA with clinical data comparing the results of the OTC use in the home to the results of subsequent formal diagnostic procedures.

Second, user validation studies should be submitted to the FDA, demonstrating that the patient can properly determine that the device is appropriate for their signs and symptoms; use the device; understand the labeling; and, finally, understand the results.

We feel very strongly that any OSA screening device should deliver unambiguous results, results that are not subject to interpretation such that a patient would definitively know whether to seek further medical assistance for their OSA.

CHAIRPERSON GULYA: You need to be

wrapping up.

MR. DUNGAN: In summary, Respironics believes that the OTC availability of oral appliances for snoring and, finally, oral screening aids is extremely important to reach a large at-risk under-served population. When supported by proper data, these two types of products can offer significant benefits to patient management.

Thank you.

CHAIRPERSON GULYA: Thank you, Mr. Dungan.

Any questions for Mr. Dungan?

(No response.)

CHAIRPERSON GULYA: Okay. Well, with that, our open public hearing session draws to a close. I thank our public speakers for the information they have taken the time and trouble to bring to the panel. I would like to turn to Sally first to see if she has any announcements or anything for the panel.

EXECUTIVE SECRETARY S. THORNTON: I don't think so, not at this time, except to say that there will be a second open public hearing session this

afternoon of a half-hour duration. And we do have one speaker at that time.

CHAIRPERSON GULYA: Well, with that, the panel has already had a pretty busy morning. I propose we take about a 15-minute break and plan on being back here at 10:30. Thank you.

(Whereupon, the foregoing matter went off the record at 10:17 a.m. and went back on the record at 10:35 a.m.)

CHAIRPERSON GULYA: We now have two panel presentations, the first of which will be by Dr. David Terris. Dr. Terris?

DR. TERRIS: Thank you.

PANEL PRESENTATIONS

DR. TERRIS: Good morning. It's an honor to have the opportunity to address this distinguished group about several issues. I was asked to take sort of an evidence-based approach to answering multiple issues. I want to start by thanking Kenny Pang, who is our sleep surgery fellow with the Medical College of Georgia, who helped with a lot of the background research.

So there were three specific issues I was asked to focus on. The first lends itself last to an evidence-based approach, which is simply a defined occurrence of standard of care for diagnosing sleep apnea; secondly, to consider the issue we have heard about already, which is, are patients capable of diagnosing themselves with having sleep apnea based on a series of signs and symptoms; and, then, finally, a related issue, which is, can they, therefore, monitor the effectiveness of treatment utilizing those same signs and symptoms and how does that correlate with objective measures of success?

I actually think it is quite important to spend just a few minutes talking about the importance of the diagnosis and treatment of sleep apnea. We have heard a little bit about this.

The cardiovascular impact we know from the sleep heart health study now, quite definitely, the impact of sleep apnea, the neurovascular risks, and the risks for motor vehicle accidents. This is an older study but quite clearly shows the impact of sleep apnea on mortality. This is from 1988, patients

with an apnea index of more than 20 or less than 20 over time untreated, you can see what happens independent of other comorbidities. This is the mortality, the cumulative survival on the y-axis.

The sleep heart health study is a very important study put on by Susan Redline and her colleagues at Wisconsin. There has been a series of publications related to this study of over 6,000 subjects enrolled. All underwent ambulatory polysomnography. And the most important finding was a very strong correlation of sleep disorders with cardiovascular disease independent of other risk factors.

We know about driving while sleeping. It's a terrible problem. National Highway Transportation Safety Administration estimates over 50,000 accidents, with 1,500 deaths, due to sleep drivers. Again, this is something we are all familiar with.

Something else most people are aware of is the Exxon Valdez crisis, but what many people don't know is that ten years after the catastrophe, it was

determined that this was caused by a sleep captain of that ship who probably had an underlying sleep disorder, so very significant ramifications.

The scope of the problem, we know that the society is becoming more obese, resulting in increased prevalence of sleep disorders and, therefore, proliferation of products to treat this problem.

This simply represents this advancing creep of obesity in society. Of course, coming from Georgia, I am particularly concerned about the dark green because that is more obesity. They are most closely associated with the prevalence of sleep apnea.

Not everybody thinks this is a problem, however.

(Laughter.)

DR. TERRIS: Well, again, proliferation of a number of different products. The snore pills, which come in a regular or allergy-type modification; the snore sprays, which are typically emollients that lubricate the upper airway; and one that we're going to consider I guess today, which is nasal strips, the Breathe Right strip. We have heard a little bit about

that. It's important to make sure it's placed accurately and depending on the nasal architecture, make sure you have enough of them.

(Laughter.)

DR. TERRIS: Oral appliances I'm going to just skip through this. There's a number of different products available, which have different ways that they're manufactured.

Okay. So getting to the issue of polysomnography, this was first described in the 1950s, popularized by Dement of Stanford in the 1960s and really is considered the gold standard today. And this is what we're talking about. Level I attended polysomnography has a series of monitors that are placed: an EEG monitor to confirm that the patient is in sleep; EOGs to test for REM sleep; EKG monitor, self-explanatory; EMG to evaluate for periodic leg movements, snoring sounds, nasal and oral air flow; and then plethysmography for chest and abdominal movements, as well as pulse oximetry and positional monitors.

I have some personal experience with this

particular modality, having had a sleep study myself about ten years ago, prior to having some minor snoring surgery.

This is what it felt like the day after the study. This is now sleep like you would at home after being hooked up to these monitors. So it's a quite involved process.

This is the information that is obtained from the sleep study. So we know that the patient is asleep. We see increasing respiratory effort but no air flow in this patient having an apnea. Therefore, they have a corresponding drop in their oxygen saturation.

Therefore, the brain has a choice to make. It wants to stay asleep, but it also need oxygen. So ultimately it usually makes the right choice and awakens so that the muscles surrounding the throat regain tone and you reestablish air flow. And, therefore, the oxygen saturation can go back up to normal.

So this is standard polysomnography. And that's in an attended in-hospital study. Ambulatory

polysomnography, which you have heard a little bit about, typically involves at least four channels looking at pulse rate, oximetry, some type of measure of air flow, and then abdominal or chest movement.

This is I think a very good way of diagnosing sleep apnea. Again, this is the modality that was utilized in the sleep heart health study. However, the ASDA has come out with a position statement in 1994 that ambulatory monitoring is no substitute for attended Level I polysomnography with the exception of rare circumstances, patient can't get to a lab or there is some contraindication to an attended in-house study.

There are a series of screening devices that are being investigated. Pulse oximetry has been utilized quite frequently. There are a number of studies examining this particular modality with sensitivity ranging from 23 percent to 90 percent. That is part of the reason why this is really considered to be a non-realizable technique for diagnosing sleep apnea.

A couple of more promising techniques.